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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/542,546	04/03/2000	Pierre Duhot	31640-159397	4816

Venable
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Washington, DC 20043-9998

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05/26/2004

EXAMINER

MCELWAIN, ELIZABETH F

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 05/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/542,546

Applicant(s)

DUHOT ET AL

Examiner

Elizabeth F. McElwain

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,12,13,17,18,20,21,23 and 30-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,12,13,17,18,20,21,23 and 30-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

The Request for Continued Examination filed March 2, 2004 has been approved and finality of the last office action has been withdrawn.

The amendment filed March 2, 2004 has been entered.

Claims 1, 12, 30 and 32-33 are newly amended.

Claims 3-11, 14-16, 19, 22 and 24-29 have been cancelled.

Claims 1, 2, 12, 13, 17, 18, 20, 21, 23 and 30-34 are drawn to the elected invention and are examined in the instant office action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any rejections that have not been repeated have been withdrawn.

Claims 1 and 12 are objected to for the recitation of "catalyzing" to characterize "a methyl transferase". Amendment of the claims to read "that catalyzes" would overcome the objection.

Claim 12 also is objected to for the recitation of "regulating" to characterize "a plant expressible promoter". Amendment of the claim to read "that regulates" would overcome the rejection.

Claim 12, and claims 13, 17-18, 20, 21, 30 and 32-34 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is indefinite in that it is unclear if the claimed promoter is limited to a promoter of a methyl transferase gene or if it may be any plant expressible promoter.

Clarification is requested.

The previously stated rejections under 112, second paragraph have been withdrawn in view of the amendment or cancellation of claims.

Claims 1, 2, 12, 13, 17, 18, 20, 21, 23, and 30-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated in the last office action.

Applicant's arguments filed March 2, 2004 have been fully considered but they are not persuasive. Applicants argue that the rejection should be withdrawn given the amendment of the claims to recite that the nucleic acid encodes a methyl transferase that transfers a methyl group to an aliphatic chain of a fatty acid and the specification discloses two methyl transferase genes. Applicants assert that the representative number required to define a genus depends on whether one skilled in the art would recognize that they were in possession of the common features of the genus of methyl transferase genes, but does not require individual support for each. Applicants argue that the specification describes several genes that were known in the prior art, and that methods for isolating other genes are provided. Finally, applicants assert

that the common feature disclosed is in catalyzing the transfer of a methyl group to an aliphatic chain of an unsaturated fatty acid.

The Examiner maintains that a description of two methyl transferases does not adequately describe the entire genus that is claimed, and that applicants have not described the structural features that are common to the genus that has as a common feature catalyzing the transfer of a methyl group to an aliphatic chain of an unsaturated fatty acid.

Claims 1, 2, 12, 13, 17-21, 23 and 30-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons set forth in the scope of enablement rejection in the last office action, wherein the specification, while being enabling for transforming tobacco with a cyclopropane fatty acid synthase gene to produce branched fatty acids in a plant, does not reasonably provide enablement for the production of branched fatty acids in any plant with any gene that encodes an enzyme that will transfer one or more alkyl groups to the double bond of an unsaturated fatty acid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated in the last office action.

Applicants' arguments filed March 2, 2004 have been fully considered but they are not persuasive. Applicants assert that the rejection should be withdrawn. Applicants argue that the articles that the Examiner relied on are not relevant to an enzyme that will transfer a methyl group, and the De Luca reference concerns secondary metabolic pathways, not primary metabolic pathways. Applicants assert that the primary metabolic pathway of which the claimed methyl transferase is a part was well known at the time of filing, as evidenced by an attached section of Lehninger, 1977. Applicants further argue that the Examiner has not explained why plants other than tobacco cannot be transformed using the teachings in the specification, in view of the successful transformation of plants since 1983. Applicants also argue that the examples are not all prophetic given that cyclopropane fatty acid synthase is a methyltransferase, and state that the Examiner has not met the burden that the scope of the claims is not adequately enabled.

The Examiner maintains that the disclosure is only enabling for transforming tobacco with a cyclopropane fatty acid synthase gene to produce branched fatty acids in a plant, and does not reasonably provide enablement for the production of branched fatty acids in any plant with any gene that encodes an enzyme that will transfer one or more alkyl groups to the double bond of an unsaturated fatty acid. The Examiner maintains that the cited references establish that without having the genes encoding methyl transferases in hand, and without having transformed a plant with said genes and establishing that branched fatty acids are produced, it cannot be established that branched fatty acids will be produced, particularly given that the methyl transferase is part of a primary metabolic pathway, as applicants have stated. While

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transforming plants with gene constructs is not unpredictable, the effects of the gene construct on a plant is not predictable, given that each plant species differs in biochemical composition with regard to the availability of precursor fatty acids and the feedback mechanisms in each species. The Examiner maintains that the teachings in the specification are only enabling for transformation of tobacco with a cyclopropane fatty acid synthase gene. Therefore, for the reasons stated in the last office action, it would require undue experimentation for one skilled in the art to make and/or use the claimed invention.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Elizabeth F. McElwain, Ph.D.

Primary Examiner

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EFM